INSTITUTE OF PUBLIC HEALTH

COLLEGE OF MEDICINE AND HEALTH SCIENCES

UNIVERSITY OF GONDAR

Treatment noncompliance rate and associated factors among tuberculosis patients at public and private tuberculosis follow up clinics in Dessie and Kombolcha, South Wollo. A comparative cross sectional study.

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A thesis submitted to the institute of public health, college of medicine and health sciences, university of Gondar in partial fulfillment of the requirements for the degree of master of public health in Epidemiology and Biostatistics.

May 2012

Dessie, Ethiopia

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ACKNOWLEDGEMENT

Firstly I would like to forward my deepest gratitude to Amhara National Regional state Health Bureau for partially funding the Research. Secondly I would like to thank my advisor Dr. Getahun Asres for his valuable comments throughout the development of this research thesis. Last but not least I would like to say thanks for all DOTS center staffs in my study area for their genuine cooperation during data collection.

LIST OF ACRONYMS

ANRSHB – Amhara National Regional State Health Bureau

AOR- Adjusted Odds Ratio

CI – Confidence Interval

COR- Crude Odds Ratio

DOTS – Directly Observed Therapy Short- course

DST- Drug Sensitivity Test

FMOH- Federal Ministry of Health

HBS$_S$- High Burden Countries

RR- Risk Ratio

INH- Isoniazid

MDR- Multi Drug Resistance

PPM- Public Private Mix

Pr. I - Principal Investigator

RHZE- Rifampicine Isoniazid Payirazinamide Etambutol

S- Streptomycin

TB- Tuberculosis

UoG-IERB- University of Gondar Institutional Ethical Review Board

WHO- World Health Organization

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ABSTRACT

Background - Non-Compliance to tuberculosis treatment is an important barrier for tuberculosis control programs because incomplete treatment may result in prolonged infectiousness, drug resistance, relapse, and death.

Objective: The objective of this study was to assess treatment compliance rate and associated factors among registered tuberculosis patients at public and private directly observed therapy short course centers in Dessie and Kombolcha, North East Ethiopia.

Methods: Facility based comparative cross sectional study was carried out among 304 tuberculosis patients attending anti tuberculosis treatment in Dessie and Kombolcha, public and private directly observed therapy short course centers. The study population was all individuals aged ≥18 years. Study subjects were selected using simple random sampling methods using patient's registration number as a frame. The Data was collected using standardized, well structured and pre-tested questionnaires which include socio-demographic and relevant compliance related variables by trained data collectors. Both bivariate and multivariate logistic regression techniques were used to analyze the data using statistical package for social science version 16.

Results

The rate of treatment non compliance was higher among patients managed at the private tuberculosis clinic (32.2%) as compared to patients managed by the public tuberculosis clinic (27.6%). Forgetfulness, use of addictive substance and unavailability of drug remained significant predictor of noncompliance both in public and private tuberculosis clinics. Herbal medication use was remained significantly associated with the level of treatment compliance only among patients attending public tuberculosis clinics, AOR (95% CI) = 5.646(2.12, 15.05). Unlike patients at public tuberculosis clinics monthly income, knowledge about tuberculosis, closure of tuberculosis clinic and health education shows significant association with noncompliance at private tuberculosis clinic.

Conclusion/recommendation

Forgetfulness, use of addictive substance and unavailability of drug were found to be the three most important factors, leading to treatment noncompliance both in public and private TB clinics. Administrative, organizational and behavioral changes involving DOTS clinics, the community, the patients and the families are necessary to improve treatment compliance. Ultimately health care professionals should provide continuous education for patients regarding the danger of treatment noncompliance. This will promote the more efficacious performance of Public Private Mix DOTS in TB control program.

Key word: Noncompliance**,** Public Private Mix-DOTS, Treatment Interruption

1. INTROCUCTION

1.1. Statement of the problem

In 2010, there were an estimated 8.8 million incident cases of TB globally, equivalent to 128 cases per 100 000 population. Ethiopia ranks seventh among the world's 22 countries with high tuberculosis burden, these countries accounts for 81% of all estimated cases worldwide. The incidence of TB of all forms and smear positive TB in Ethiopia stands at 261 and 152 per 100,000 population, respectively with a mortality of tuberculosis of all forms excluding HIV is estimated to be 35 per 100,000 populations (1).

According to the World Health Organization (WHO), directly observed therapy short course (DOTS) ensures successful treatment of patients with tuberculosis. Ethiopia has used DOTS since 1992, but it was limited to public health facilities until 2006. However, the FMOH had a strong interest in expanding DOTS services in line with WHO global recommendations to involve the private sector in the delivery of TB service (2). As of December-2010 there is 213 public private mix (PPM) sites providing DOTS in Ethiopia, of this 35 are in Amhara region (3). Despite a rapid expansion of TB health care facilities tuberculosis remains the leading cause of morbidity, the third cause of hospital admission and the second cause of death in Ethiopia (4).

Non-compliance with tuberculosis treatment has many adverse consequences, not only for patients and their families, but also for society, in the form of increased drug resistance. The data from drug sensitivity test(DST) survey conducted in Ethiopia between 2003 and 2006 shows that the level of MDR-TB are 1.6% and 11.8% in new cases and re-treatment cases of TB patients, respectively(5). MDR-TB reflects the poor primary management of the disease. It is mainly caused by the failure to ensure compliance, rather than the failure of the drugs to cure. The highest priority in fighting MDR-TB therefore must be its prevention (5). A case control study in Uganda conducted to determine the predictors of treatment failure among patients with sputum smear positive pulmonary TB shows poor adherence to anti TB treatment (OR 14.59, 95%CI 3.04-70.15) is a significant predictors of treatment failure (6).

Another similar study done in Egypt shows non compliance is significant risk factor for treatment failure (7). A study aimed to identify factors associated with tuberculosis recurrence in patients treated with the short-course regimen in Brazil shows as noncompliance [RR = 6.43 (95% CI: 2.02-20.44)] is proved to be independently associated with recurrence of tuberculosis (8).

A high treatment default rate (10-20%) was described in Ethiopia which adversely affected the national cure rate (9, 10). In an effort to reach the national as well as global target of 85% treatment success and noncompliance rates of TB programs be lower than 5%((1). It was wise to identify, describe, and deal with factors determining treatment compliance. The current study, therefore, aims at determining factors that predict treatment compliance among TB patients attending TB treatment in public and private health institutions in Dessie and Kombolcha, Amhara region, North East Ethiopia.

1.2. Literature review

Compliance to TB treatment

Tuberculosis can be cured only if the anti-TB drugs are taken regularly. People with tuberculosis require treatment for at least six to eight months. New TB patients (category-I) are treated with 2 months of (RHZE) and 4 months of (RH) and the treatment regimen for re-treatment (category II) adults is 2 month of S(RHZE), 1month of (RHZE) and 5 month of (RH)E. Many find it difficult to complete their course of treatment and this serves as a major constraint to eradicating the disease. The uninterrupted availability of drugs and precise organization of treatment delivery will ensure patients' compliance with treatment (3).

Magnitude of Non Compliance

A prospective cohort study in Awassa, South Ethiopia describes a default rate of 20 %(9). Another study in Oromia Region, Arsi Zone, Ethiopia shows the overall rate of defaulting from DOTS was 11.3%, while the rate in sputum smear-positive cases was 11.6%(10). However a higher rate of non compliance (49.2%) was registered in a community based cross sectional study in Gondar, North West Ethiopia (11). A study in south India shows a default rate of 20 %(12). A comparable figure (21% and 23%) was described in Jiangsu province, China and Sri Lanka respectively (13, 14).

Another study in Jiangsu province in china found that 12% of patients did not take at least 10% of their prescribed doses of anti-TB treatment (15).

A larger proportion (46%) of patients missed at least 10% of the doses as indicated by a study in Hebei Province, china (16).

A survey of 45 private for profit practitioners in Philippines asked health workers what they believed was the percentage of their patients who regularly took treatment up to the end. Majority of the respondent estimate between 30 and 70% of their TB patients were non adherent (17).

A systematic review of studies evaluating the impact of public and private healthcare provision on TB treatment outcomes describes four of the six studies found that patients in a private healthcare facility were more likely to interrupt TB treatment than patients in public healthcare facility OR 2.04 (95% CI 1.07– 3.89(18). Similarly a study in Delhi, India shows higher rate of treatment interruption in the private health sector (56.27%) as compared to public DOTS (34.25%)(19). Another study in Thailand also found higher rate of default in private facilities (92%) compared with (41%) in small and (40%) in large public facilities ($P < 0.01$, both comparisons) (20).

However a comparative cross- sectional descriptive study comparing the public and private facilities providing DOTS services in Nigeria shows a higher defaulter rate among patients managed by public health facilities (13.0%) compared to only 5.8% among patients managed by the private facilities (21). Similarly a study in Bengal shows a higher rate of default in public hospital 29.30 % compared to only 10.78% in private hospitals(22).

FACTORS ASSOCIATED WITH TREATMENT COMPLIANCE

Socio Demographic Factors

Different study in Kenya, Thailand, India show being male was associated with high non compliance rate (20, 23, 24). While a study in Malaysia identifies no sex difference to become non compliant (25).

A prospective cohort study conducted in Awassa, South Ethiopia identifies age >25 years (RR = 1.71; p = 0.02) was associated with defaulting from treatment (9). Similarly a study in Thailand found that older age is associated with defaulting (20).

A study in India shows the percentage of defaulters continued to remain high in the older age groups both in private and public facilities (22). However a study in Malaysia identifies no statistical significance for age between compliant and non compliant patients (25).

A statistically significant (*P* = 0.043) difference was seen in non-compliant between single (17.5%), married (27.8%) and other (widowed and divorced) participants (50%) in Nepal (26). Similar to public facilities being widowed or divorced were found to be associated with unsuccessful treatment outcomes in private health facilities (20).

Studies in China, Thailand, and South Africa shows increasing educational status were associated with a lower non compliance rate (15,25, 27). A study in India shows the proportion of defaulters decreased uniformly with increasing educational status, the difference being significant ($p<0.05$) uniformly both in public and private DOTS centers (22).

Different studies in Gondar, Ethiopia and Nairobi, Kenya indicate Low income was significantly associated with non compliance (11, 23). In contrast to that a study in Malaysia shows high income groups are high risk for non compliance (25). A comparative study in India shows with increasing family monthly income, the percentage of defaulters decreased uniformly both in the private and public health facilities (22). However a study in Arsi Zone, Ethiopia shows no difference between compliant and non compliant groups regarding monthly family income (10).

Patient related factors

A case control studies in Arsi Zone, Ethiopia and Kenya, identifies adequate knowledge to TB were found to be possible protective factors for non compliance (10, 23). Other different studies in India and Nepal describes similar finding(26, 28). However a study in Malaysia shows no statistically significant differences between compliant and non compliant groups for knowledge (25).

A study in Gondar, Ethiopia done to assess the magnitude and factors of non compliance with medication prescribed for chronic disease describes the reasons why patients don't comply with drug regimens as forgetfulness(11). Alcoholism was described as a significant predictive factor for non compliance in different studies (12, 24, 27, 28).

Social related factors

Family support was found to be possible protective factors for non compliance as described by a study in Arsi, Ethiopia (10). Studies in China found that observation of treatment by volunteers and village doctors tended to decrease the chance of non-compliance ($p = 0.06$)(13, 15). Similarly a study in India revealed that the patients who were observed by Government DOTS workers defaulted twice than that of observed by volunteers (29).

A study in Jiangsu province in China shows social stigma was a significant risk factor for non compliance (15). Another study in South Africa reveled that feeling ashamed to have TB (AOR 2.0, 95% CI 1.3–3.0) was associated with non compliance(27).

A retrospective case-control study in Nairobi, Kenya indicates herbal medication use was significantly associated with default (23). Similar study in South Africa describes seeing a traditional healer during TB treatment was a significant predictor of non compliance (27).

Health Care and System Related Factors

A study in Awassa, South Ethiopia identifies distance from home to treatment centre (HR] = 2.97; $p < 0.001$) was associated with defaulting from treatment. In addition the study describes necessity to use public transport to get to a treatment centre (HR =

1.59; p = 0.06) was associated with defaulting from treatment (9). In contrast different studies in Arsi zone, Ethiopia and Nepal show no statistically significant differences in distance and mode of travel between compliant and non compliant groups. However, shorter travelling time was associated with better adherence (10, 26).

Inadequate patient provider interaction [OR-1.72], no support from health staff [OR-1.93), dissatisfied with services [OR-1.73) were associated with non compliance as described by a study in India (28). Similar findings were described in a study conducted in South Africa (27).

As shown by a study conducted in Nepal compliant patients were almost twice as likely to mention the availability of health education (87%) than non-compliant patients (47%) (*P* = 0.001). About 75% of compliant versus 49% of non-compliant patients confirmed the presence of daily DOTS at the clinics they attended (*P* = 0.001). Availability of drugs and health workers at every visit does not show differences between compliant and non compliant groups in this study (26).

Studies in Nepal and South Africa describes daily health education and counseling about TB treatment was independently associated with compliance (26, 27).

A study in south India shows factors for default were inconvenience for DOTS time(12).

Treatment/ disease related Variables

Different studies in Ethiopia and other countries describes medication side effects was significantly associated with defaulting (10, 11, 13-15). However no statistically significant differences were found between compliant and non compliant groups to medication side effects in a study conducted in Malaysia (25).

Studies conducted in Delhi, India and South Africa shows early improvement is the most common reasons leading to treatment interruption (19, 27). Similar finding was also described for private health facilities in a study conducted in Philippines (17).

A case-control study in Nairobi, Kenya indicates co-infection with Human immune-deficient Virus (HIV) were significantly associated with default (23). Another study in India also describes having other concomitant diseases during treatment [OR-3.22 were independently associated with default (28).

1.3. Justification of the proposed study

Treatment non compliance is required to fall below 5% in order to achieve treatment success of 85%, one of the targets in WHO STOP TB strategy. To achieve this target Ethiopia expands the DOTS service to private health institutions starting from 2006 in line with WHO global recommendation to involve the private sector in the delivery of TB services. Some studies done in public DOTS centers shows higher non compliance rate and as no study is done in private DOTS centers nationally as well as in this study area, the current study, therefore, investigated compliance rate and factors that predict treatment compliance among registered TB patients in Dessie and Kombolcha, North East Ethiopia. The finding of this study aimed at developing targeted measures to scaled-up the Public private mix (PP-M) DOTS strategy to improve patient compliance and thereby preventing treatment failure, recurrence, drug resistance and Death.

2. OBJECTIVE

2.1. General objective

To assess treatment noncompliance rate and associated factors among registered TB patients at public and private DOTS clinics in Dessie and Kombolcha, North East Ethiopia from April 02 to May 04, 2012.

2.2. Specific objectives

- To compare noncompliance rate to drug treatment among registered TB patients at public and private DOTS clinics in Dessie and Kombolcha.
- To identify factors affecting noncompliance to tuberculosis drug treatment among TB patients at public and private DOTS clinics in Dessie and Kombolcha.

3. METHODS

3.1. Study design

A facility based comparative cross sectional study between public and private DOTS clinics was conducted to assess treatment compliance rate and associated factors among TB patients.

3.2. Study area and period

The study was conducted at public and private health facilities which provide DOTS services in Dessie and Kombolcha town which are 380 – 400Km, North-East of Addis Ababa from April 02 to May 04, 2012.

Administratively Dessie town is divided into 21 Kebeles. According to central statistics agency population census 2007, the population of the town is estimated to be 151,094.

Based on figures from the Central Statistical Agency in 2007, Kombolcha has an estimated total population of 85,337. The town has divided with five Kebeles with an estimated area of 8.66 square kilometers.

There is one referral hospital, one general hospital, three health centers, four upgrading health centers and six health posts owned by the government in Dessie. Concerning private health facilities there are three private general hospitals, six higher clinics, five medium clinics, sixteen junior clinics. From these health facilities the DOTS service is provided at Dessie referral hospital, Boru-Meda hospital, all of the health centers, all the three private general hospitals, four of the private higher clinics. Based on South Wollo Zonal Health Department TB report for 2003, TB case detection rate in Dessie town was 62%.

DOTS service was given at three public health center and two private medium clinics in Kombolcha town.

Tuberculosis cure rate in Dessie and Kombolcha were 73% and 75.4%, respectively in 2004 E.C.

3.3. Source population

All registered adult tuberculosis patients at public and private health institutions in South Wollo Zone, North East Ethiopia.

3.4. Study population

All registered adult TB patients attending their DOTS treatment in public and private health facilities in Dessie and Kombolcha, South Wollo during the specified study period.

3.5. Inclusion and exclusion criteria

3.5.1. Inclusion criteria

Tuberculosis patients aged18 years old and above were included in this study. Patients who had completed two week of treatment days or more were included, as we thought that they would have more exposure to DOTS and could contribute their feelings and experiences more extensively during the interview

3.5.2. Exclusion criteria

Patients with mental disorder, severely ill and individuals who are unable to hear were excluded from the study. In addition those patients who are transferred in were also not included in this study.

3.6. Sample size

The required sample size for the study was determined using EPI INFO statistical software version 3.3.2 based on the following assumptions

- p1= 40 %(proportion of non compliant TB patients in public DOTS taken from a study done in N/Wollo in 2009(30).
- OR=2
- Confidence level or 1- α = 95%
- Power or 1- β = 80%
- Ratio (number of subjects in public DOTS/ number of subjects in private DOTS) = 1:1 Fitting the above assumptions in to the software the required minimum sample size is 144 in each group. Adding 5% for non response rate the final sample size was 152 from each group

3.7. Sampling procedures:

A total of around 442 TB patients were registered at eight public and seven private health facilities providing DOTS for tuberculosis during the time of data collection in the study area, 170 of them were registered in private DOTS clinics. From private DOTS we took all patients who fulfill our inclusion criteria when they come to take their drug until our sample reached 152, we thought that the nature of registration of patients by itself were random. However proportional allocation to size was used to select 152 patients using simple random sampling technique from 272 registered TB patients at public DOTS using the registration list of patients as a frame.

3.8. Variables of the study:

Dependent variable – compliance to anti TB drug treatment (Yes or No)

Independent variables:

Patient related Variables

1. Socio demographic variables (sex, age. marital status, educational status, occupation etc)
2. Residence
3. Monthly household income
4. Forgetfulness to take the drug
5. Knowledge on TB
6. Substance abuse

Health care and system related variables

1. Type of Health Facility(public Vs private)
2. Distance (DOTS center to patient home)
3. waiting time
4. Availability of drug on scheduled days
5. Health education
6. DOTS time
7. Availability of health worker on scheduled days

Social related variables

1. Stigma
2. Treatment Supporter
3. Use of herbal medicine

Treatment/ disease related Variables

1. Side effect of drugs
2. Early improvement
3. Co morbidity
4. Type of TB

3.9. Operational definitions:

- **Compliant** - A patient was defined compliant to treatment if the proportion of actual doses taken of those prescribed was greater than 95%.
- **Non** -**Compliant** - Patients who had missed 5% or more of the total prescribed dose of TB drugs were classified as noncompliant.
- **Long waiting time** –Staying more than one hour to take/collect the drug at DOTS center.
- **Adequate knowledge about TB** – A patient who scores more than three from a six item questions asked to measure TB knowledge. These questions were derived from information routinely provided to patients as part of the national TB program. A correct response was scored with one point. Incorrect or missing responses were scored with zero points. A total TB knowledge score was created by summing the scores for all questions. The score ranged from 0 to 6.
- **Inaccessible DOTS center –** DOTS center located >5Km far from patient home.
- **Treatment Interruption-** Patients who had missed 1% or more of the total prescribed dose of TB drugs were classified as treatment interrupter.
- **Use of Addictive Substance –** A patient who has currently used one or more of cigarette smoking, alcohol drinking and chat chewing.

3.10. Data collection procedures (instrument, personnel)

Data collection was carried out by fifteen health professionals (accelerated midwife trainers at Dessie health Science College and nurses) who were given a one day intensive training with practical exercises. One health officers and two degree holder nurses were assigned to supervise the data collection process and the overall coordination was handled by the principal investigator. The interview was conducted in the nurse office after the patient is served. The data was supplemented by patient medical record review and pill count.

3.11. Data quality control measures

To keep the quality of data Standardized structured questionnaire was used. The English version questionnaire was translated in to Amharic (local language) and then back to English to maintain its consistence for actual data collection purpose.

The questionnaire was also pre-tested for their accuracy and consistency prior to actual data collection in Haik (neighboring district) DOTS clinic. Furthermore, the supervisor and the principal investigator gave feedback and correction on daily basis for the data collectors before they start daily data collection. Completeness, accuracy, and clarity of the collected data were checked carefully. Finally the collected data were entered in to computer using EPI-INFO to maintain its quality.

3.12. Data processing and analysis

Data entry into the computer was carried out using **epi Info** version 3.5.1 and then transferred to the Statistical Package for Social Sciences (SPSS) for Windows version 16 for analysis. The main statistical method applied was binary logistic regression and both bivariate and multivariate analyses were considered. The unadjusted (crude) and adjusted Odds ratios together with their corresponding 95% confidence intervals were computed. A P-value ≤ 0.05 was considered statistically significant in this study. Efforts were made to assess whether the necessary assumptions for the application of multiple logistic regression were fulfilled. In this regard, the Hosmer and Lemeshow's goodness-of-fit test was considered. A good fit as measured by Hosmer and Lemeshow's test will yield a large P-value.

4. ETHICAL CONSIDERATIONS

Ethical clearance was obtained from Institutional Review Board of UoG. In addition permission to conduct the study was obtained from Amhara Regional Health Bureau, South Wollo Health Department and Woreda Health Office and from each Health Facilities prior to data collection. Objective of the study was clearly explained for participants before conducting the interview and written consent was obtained from each participant after voluntary participation feature of the study are explained. Individual records were coded and accessed only by research staff. In addition no information that identifies individual patients was filled on the data collection format. The recorded data has kept in a secured place with strict confidentiality. Immediate health education regarding the danger of treatment interruption was given for participants after data collection emphasizing more on non compliant patients.

5. DISSEMINATION OF RESULTS

The finding will be disseminated to UoG, ANRSHB, South Wollo health department and District health office through hard copy, conference presentation and others though publication on journals.

6. RESULTS

Socio-demographic characteristics of the respondents

A total of 152 TB patients from public and 152 TB patients from private DOTS clinic, aged ≥18 years were included by the study, making a response rate of 100%. Of which 158(52 %) were male and 146(48 %) were females. The mean (SD) age for TB patients from public and private DOTS clinic were 32 (12) and 33(13), respectively. The overall mean age (SD) was 32(13) years, ranging from 18 to 70 years. About 50% of the respondents in both groups were young in the age group 18-29 years. Majority of the patients 262(86.2%) were from the urban areas of Dessie and Kombolcha city. Almost all respondents were from Amhara ethnic group, 282(92.8%). About two- third of the patients were self-employed; students constitute 15.1% of the respondents. Over two – third of the patients were from families with monthly household income of 500-1000 ETB. Islam was the main religion for about 53.3% of the respondents followed by Orthodox Christian which constituted nearly 42.8% of the overall study subjects. About 41 (27 %) and 56 (36.8%) of TB patients from public and private DOTS clinic have attended secondary schooling, respectively. Table 1 shows socio-demographic characteristics of study population.

Table 1: Socio demographic characteristics of TB patients at public and private DOTS clinic in Dessie and Kombolcha. South Wollo from April 02 to May 04, 2012.

Variable		Health Facility		Total (304) Count (%)
		Public(n=152) Count (%)	Private(n=152) Count (%)	
Sex	Male	84(55.3)	74(48.7)	158(52)
	Female	68(44.7)	78(51.3)	146(48)
Age	18-29	83(54.6)	69(45.4)	152(50)
	30-41	38(25)	48(31.6)	86(28.3)
	42+	31(20.4)	35(23)	66(21.7)
Residence	Urban	131(86.2)	131(86.2)	262(86.2)
	Rural	21(13.8)	21(13.8)	42(13.8)
Religion	Islam	91(59.9)	71(46.7)	162(53.3)
	Orthodox	56(36.8)	74(48.8)	130(42.8)
	Protestant	5(3.3)	7(4.6)	12(3.9)

Table 1 continued

Ethnicity	Amhara	147(96.7)	135(88.8)	282(92.8)
	Others	5(3.3)	17(11.2)	22(7.2)
Marital status	Married	65(42.8)	70(46.1)	135(44.4)
	Single	68(44.7)	63(41.4)	131(43.1)
	Divorced/separated	19(12.5)	19(12.5)	38(12.5)
Educational status	No formal schooling	34(22.4)	26(17.1)	60(19.7)
	Primary	45(29.6)	19(12.5)	64(21.1)
	secondary	41(27.0)	56(36.8)	97(31.9)
	12+	32(21.1)	51(33.6)	83(27.3)
Occupational status	Gov't Employee	26(17.1)	27(17.8)	53(17.4)
	Self employed	49(32.2)	43(28.3)	92(30.3)
	Unemployed	42(27.6)	37(24.3)	79(26.0)
	Housewife	14(9.2)	20(13.2)	34(11.2)
	Student	21(13.8)	25(16.4)	46(15.1)
Monthly household income	≤500	61(40.1)	31(20.4)	92(30.3)
	501-1000	52(34.2)	53(34.9)	105(34.5)
	1001-1499	21(13.8)	35(23.0)	56(18.4)
	≥1500	18(11.8)	33(21.7)	51(16.8)

Disease characteristics and compliance level of the respondents

As shown in Table 2, overall, 93.8% of the patients were new cases of TB. There were fifteen patients from public and four patients from private DOTS clinics on retreatment . Sixty percent of the overall respondents have a type of pulmonary tuberculosis (PTB +ve 33% and PTB-ve 27%). The reaming patients (40%) were categorized as having extra pulmonary tuberculosis. About 40% of the respondents from both groups have a history of missing at least a dose of their treatment. Among all patients seen in both public and private DOTS clinics a non- compliance rate of 29.9% was attained. The rate of treatment non compliance was higher among patients managed by the private DOTS clinic (32.2%) as compared to patients managed by the public DOTS clinic (27.6%).

Table 2: Disease characteristics and compliance level of TB patients at public and private DOTS clinic in Dessie and Kombolcha. South Wollo from April 02 to May 04, 2012.

	Public(n=152) Count (%)	Private(n=152) Count (%)	Total(n=304) Count (%)
Case category			
New	137(90.1)	148(97.4)	285(93.8)
Re-treatment	15(9.9)	4(2.6)	19(6.2)
Disease category			
PTB +	51(33.6)	50(32.9)	101(33.2)
PTB -	46(30.6)	35(23.0)	81(26.6)
EPTB	55(36.2)	67(44.1)	122(40.1)
History of TB treatment Interruption			
Yes	59(38.8)	63(41.4)	122(40.1)
No	93(61.2)	89(58.6)	182(59.9)
Compliance level			
Compliant	110(72.4)	103(67.8)	213(70.1)
Non compliant	42(27.6)	49(32 .2)	91(29.9)

Associated factors affecting the level of treatment compliance as a whole

As can be noted from table 3 six variables show significant association at a 5% level of significant during multivariate analysis. In this regard type of health facility, family income, opening time, distance, and waiting time, closure of TB clinic, stigma, treatment supporter, side effect, improvement and phase of TB treatment does not show significant association with compliance level.

However forgetfulness, use of addictive substance, knowledge about TB, availability of drug, health education, and herbal medication use remained significantly and independently associated with compliance level at multivariate analysis

Table-3: Binary logistic regression output showing associated factors affecting the level of compliance to drug treatment for the study population as a whole, Dessie & Kombolcha. (Bivariate and multivariate analysis, n=304)

Variables		Compliance level		COR(95%CI)	AOR(95%CI)
		Compliant	Non compliant		
Health facility	Public	110	42	17	
	Private	103	49	1.25(0.76,2.01)	
Monthly household income					
	≤500	58	34	1	
	501-1000	71	34	0.82(0.45,1.47)	
	1001-1499	45	11	0.42(0.19,0.91)	
	≥1500	39	12	0.52(0.24,1.14)	
Forgetfulness	No	177	48	1	1
	Yes	36	43	4.41(2.55,7.60)	3.45(1.85, 6.46)*
Use of Addictive substance					
	No	172	49	1	1
	Yes	41	42	3.59(2.11, 6.14)	2.62(1.42, 4.83)*
Knowledge of TB	Adequate	184	57	1	1
	Not Adequate	29	34	3.78(2.12, 6.74)	2.59(1.31, 5.09)*
Opening Time	Convenient	64	37	1	
	Not Convenient	149	54	0.63(0.37, 1.04)	
Distance to treatment center					
	≤ 5Km	189	74	1	
	>5Km	24	17	1.81(0.92, 3.56)	
Waiting Time	≤1 hour	171	63	1	
	>1hour	42	28	1.81(1.03, 3.16)	
Availability of Drug					
Always Available		191	64	1	1
Not Always Available		22	27	3.66(1.95, 6.88)	3.13(1.48, 6.61)*
Closure of TB clinic					
	No	196	75	1	
	Yes	17	16	2.46(1.18, 5.12)	

Table 3 cont…

Variables		Compliance level		COR(95%CI)	AOR(95%CI)
		Compliant	Non compliant		
Get Health	Yes	154	44	1	1
Education	No	59	47	2.78(1.67, 4.64)	1.98(1.09, 3.61)*
Stigma	No	191	75	1	
	Yes	22	16	1.85(0.92, 3.72)	
Has Treatment Supporter					
	Yes	190	73	1	
	No	23	18	2.03(1.01, 3.99)	
Herbal Medication Use					
	No	180	53	1	1
	Yes	33	38	3.91(2.24, 6.83)	3.07(1.58, 5.95)*
Side effect	No	81	24	1	
	Yes	132	67	1.71(0.99, 2.94)	
Improvement	Late	99	53	1	
	Early	114	38	0.62(0.38, 1.02)	
Phase of TB treatment					
	Intensive	109	36	1	
	Continuation	104	55	1.60(0.97, 2.64)	

* remained significant in multivariate analysis at a 0.05 level of significance.

Associated factors affecting the level of treatment compliance separately at public and private DOTS

Socio demographic, patient, facility and disease related determinants in relation to treatment compliance were analyzed by bivariate and multivariate analyses using binary logistic regression model. As can be noted from the findings of the bivariate analyses (Tables 4 and 5), six of the twenty three variables from public DOTS and ten of the twenty three variables from private DOTS clinic shows a significant association with the outcome variable at a 5% level of significance. In this regard forgetfulness, substance abuse, knowledge about TB, availability of drug, health education and herbal medication

use shows significant association with the level of treatment compliance both in patients at public and private DOTS clinic. In addition marital status, distance to treatment center, waiting time and closure of TB clinic significantly related with treatment compliance only in patients attending at private DOTS clinics.

The multivariate logistic regression analysis which controls the undesirable effects of confounding variables was used by taking all predictor variables into account simultaneously. Each of these predictor variables showed statistical significance at a 0.2 level of significance (Tables 4 and 5).

The backward stepwise regression which controls the problem of multi co linearity was employed and only four and seven of the contributing factors remained to be significantly and independently associated with the level of treatment compliance among patients at public DOTS clinic and private DOTS clinic, respectively. In this regard forgetfulness, use of addictive substance and availability of drug remained significant both in public and private DOTS clinics. Herbal medication use was remained significantly associated with the level of treatment compliance only among patients attending public DOTS clinics. Unlike patients at public DOTS clinics monthly income, knowledge about TB, closure of TB clinic and health education shows significant association with the outcome variable in multivariate analysis for patients serving at private DOTS clinic.

Accordingly, patients at public DOTS clinic who forget taking daily dose of their treatment were 4.75 times more likely to be non compliant as compared to those who does not forget their daily treatment (AOR = 4.75, 95%CI: 1.96, 11.48). However, the difference in the level of treatment compliance between patients at private DOTS clinic who forget and does not forget taking daily dose of their drug shows marginal significance (AOR=2.39, 95% CI: 0.91, 6.24).

Those patients who currently use addictive substance were more likely to be non compliant both in patients attending public and private DOTS clinics ((AOR (95%CI):3.54(1.34, 9.37), AOR (95%CI):2.61(1.11, 6.24), respectively).

Table-4: Binary logistic regression output showing associated factors affecting the level of compliance to drug treatment among TB patients attending treatment at public DOTS center, South Wollo. (Bivariate and Multivariate analysis, n=152)

Variables	Compliance level		COR(95%CI)	AOR(95%CI)
	Compliant	Noncompliant		
Monthly household income				
≤500	43	18	1	
501-1000	34	18	1.26(0.572,2.796)	
1001-1499	19	2	0.25(0.053,1.194)	
≥1500	14	4	0.68(0.198,2.359)	
Forgetfulness*				
No	91	20	1	1
Yes	19	22	5.27(2.41,11.51)	4.752(1.966,11.48)
Substance Abuse*				
No	97	27	1	1
Yes	13	15	4.15(1.76,9.76)	3.54(1.336,9.37)
Knowledge of TB				
Adequate	95	29	1	
Not Adequate	15	13	2.84(1.21,6.65)	
Availability of Drug *				
Always Available	95	29	1	1
Not Always Available	15	13	2.839(1.21,6.65)	3.084(1.141,8.33)
Health Education				
Yes	79	20	1	
No	31	22	2.80(1.34,5.842)	
Herbal Medication Use *				
No	98	26	1	1
Yes	12	16	5.026(2.12,11.93)	5.646(2.12,15.05)

* remained significant in multivariate analysis at a 0.05 level of significance.

Table-5: Binary logistic regression output showing associated factors affecting the level of compliance to drug treatment among TB patients attending treatment at private DOTS center, South Wollo. (Bivariate and Multivariate analysis, n=152)

Variables		Compliance level		COR(95%CI)	AOR(95%CI)
		Compliant	Noncompliant		
Sex	Female	57	21	1	
	Male	46	28	1.652(0.83,3.28	
Marital status					
	Single	38	25	1	
	Married	55	15	0.415(0.19,0.89)	
	Divorced/separated	10	9	1.368(0.48,3.84)	
Monthly household income*					
	≤500	15	16	1	1
	500-1000	37	16	0.405(0.16,1.01)	0.196(0.06, 0.64)
	1001-1499	26	9	0.325(0.12,0.91)	0.272(0.08, 0.92)
	≥1500	25	8	0.300(0.104,0.87)	0.199(0.05, 0.73)
Forgetfulness **					
	No	86	28	1	1
	Yes	17	21	3.794(1.76,8.18)	2.39(0.91,6.24)
Substance abuse *					
	No	75	22	1	1
	Yes	28	27	3.287(1.62,6.69)	2.605(1.108, 6.24)
Knowledge of TB*					
	Adequate	89	28	1	1
	Not Adequate	14	21	4.768(2.15,10.59)	3.460(1.37, 8.75)
Opening Time					
	Convenient	35	22	1	
	Not Convenient	68	27	0.632(0.32,1.27)	
Distance					
	≤ 5Km	90	36	1	
	>5Km	13	13	2.500(1.06,5.91)	
Waiting Time					
	≤1 hour	84	31	1	
	>1hour	19	18	2.567(1.19,5.52)	

Table 5 continued

Availability of Drug*				
Always Available	96	35	1	1
Not Always Available	7	14	5.486(2.04,14.71)	3.447(1.08,10.95)
Closure of TB clinic*				
No	92	36	1	1
Yes	11	13	3.020(1.24,7.36)	3.077(1.01, 9.40)
Get Health Education*				
Yes	71	21	1	1
No	32	28	2.958(1.46,5.97)	2.742(1.14, 6.57)
Stigma				
No	93	40	1	
Yes	10	9	2.092(0.79,5.54)	
Has Treatment Supporter				
Yes	93	39	1	
No	10	10	2.385(0.92,6.18)	
Herbal Medication Use				
No	82	27	1	
Yes	21	22	3.182(1.52,6.66)	
Side effect				
No	37	11	1	
Yes	66	38	1.937(0.88,4.23)	
Improvement				
Late	61	35	1	
Early	42	14	0.581(0.28,1.21)	
Phase of TB treatment				
Intensive	47	15	1	
Continuation	56	34	1.902(0.93,3.91)	

* remained significant in multivariate analysis at a 0.05 level of significance.

** Shows marginal significant in multivariate analysis at a 0.05 level of significance

Patients who mentioned unavailability of drug at each scheduled day where high risk for treatment non compliance, their risk is more than 3 times both in public and private DOTS when compared to patients who mentioned availability drug in all their visits. Our result shows herbal medication use where significantly and independently associated with noncompliance among patients attending public DOTS clinics (AOR=5.65, 95%CI=2.12, 15.05). The difference in the variable between public and private DOTS were significant (P=0.042)

Patients attending private DOTS clinic who have higher monthly income were less likely to be noncompliant as compared to low income groups (AOR=0.19, 95%CI=0.05, 0.73). Economically better patients were among patients attending private DOTS, the difference was significance when compared to patients at public DOTS (p=0.001).

Patients' Knowledge about TB does not show significance difference at public DOTS clinics. But those patients at private DOTS with inadequate knowledge were 3.46 times high risk for noncompliance (AOR=3.601, 95%CI=1.37, 8.75). Closure of TB clinic at private DOTS was significantly associated with noncompliance, but it does not at public DOTS. The difference was significant between the two groups (p = 0.04). Private DOTS who close their clinic at a scheduled day contribute a threefold increase in risk of noncompliance for their patients. A significant number of patients attending private DOTS clinics reported that they do not receive regular counseling and health education about their treatment regimen and DOTS. These patients were 2.74 times more likely to be noncompliant as compared to those who had get health education by health workers (AOR=2.74, 95%CI=1.14, 6.57).

The assessment made whether the required assumptions for the application of multiple logistic regression was fulfilled showed that the model adequately fits the data (Hosmer Lemeshow test as P- value= 0.15, 0.56 and 0.18 for Overall, at public and at private DOTS, respectively)

Reasons for interrupting treatment

Of the 304 patients, 122 (40.1 %) stopped taking their treatment at some point. Of these, 91(29.9%) were non compliant (Interrupt at least 5% of their daily dose of treatment). Most patients who have a history of treatment interruption gave multiple reasons for interruption of daily dose of their treatment. Traveled to other area 25(20.49%) and forgetfulness 21 (17.21%) were the most frequently mentioned reasons. Around 20 (16.4%) of the interrupters said their interruption was due to unavailability of drug at the clinic during a scheduled time. Other reasons includes: lack of family support 16 (13%), early improvement 17(14%), severe illness 15(12%), not being told to regular treatment 14(11.5%), herbal medication use 14(11.5%), working busy 14 (11.5%), side effect 11(9%) and others 7(5.74%).The percentage was greater than 100% because of multiple responses. Figure 1: illustrates the reasons mentioned for treatment interruption.

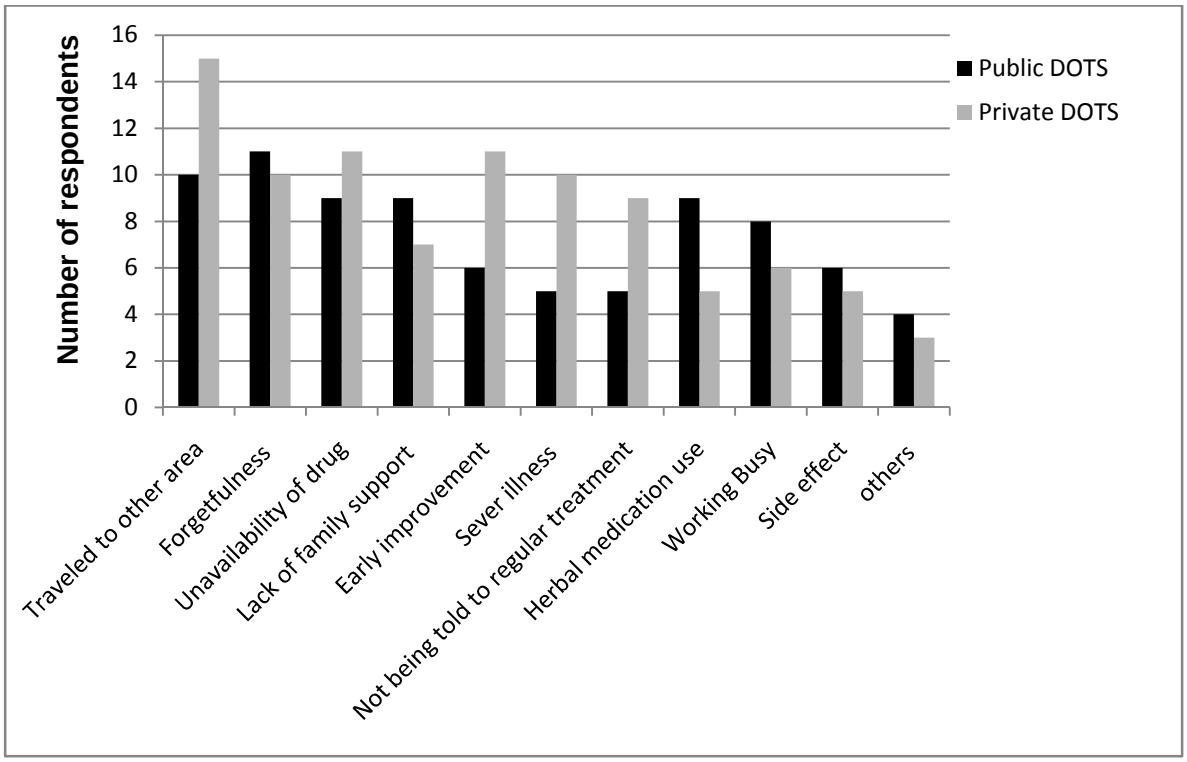

Figure 1 Reasons for treatment interruption given by the respondents who have a history of interrupting daily dose of treatment by type of DOTS clinics (n=122)

(Others: distance, unable to afford travel cost, inconvenient opening time)

7. DISCUSSION

Non-compliance is cited as a major obstacle to the control of tuberculosis at the level of public health (15, 16).It is also a serious problem in the treatment of individual patients and in the development of drug resistant strains. Therefore, this study has attempted to look into the level of compliance in public and private set ups by incorporating as many risk factors as possible.

Our results show that noncompliance rates were higher among patients attending private DOTS clinic (32.2%) than among those patients attending public DOTS clinics (27.6%). This may be due to private DOTS clinic did not strictly adhere to the guidelines recommended in the DOTS strategy. These finding was higher as compared to studies done in Arsi Zone and Southern Ethiopia, they investigate a defaulting rate of 11.3% and 20%, respectively(1, 2). This may be due to the use of higher cut point used to say noncompliant in those studies (25%). In other ways noncompliance rate of this study was lower as compared to a study done in India which describes a noncompliance rate of 56.27% in private DOTS clinics and 34.25% in public DOTS clinics (3). However a comparative cross- sectional descriptive study comparing the public and private facilities providing DOTS services in Nigeria shows a higher rate of default in public hospital 29.30 % compared to only 10.78% in private hospitals(22). This shows a better private health care system in those countries.

This study shows that the main factors influencing noncompliance to Anti TB drugs both in patients at public and private DOTS clinics were forgetfulness, use of addictive substance and unavailability of drug at every visit.

Forgetfulness significantly increases the risk of noncompliance. This may be due to the behavioral nature of the variable and passive participation of treatment supporters. The same finding was stated in a study done in Gondar, Ethiopa (11).

Our study established that noncompliance was higher in those patients who have currently use addictive substance, as was shown in different studies (12, 24, 27, 28). The reason behind that may be addictive patients are not interested in following their treatment daily and they have a sleep pattern usually in the morning, causes to miss taking daily dose.

A study from Nepal reported that unavailability of drug at every visit in the treatment center does not show significant difference between compliant and non compliant groups (26). In the present study unavailability of drug was a significant predictor of noncompliance among TB patients both in public and private DOTS clinic. Poor coordination and disorganized management of drug resources throughout the health care system in our country makes the difference.

The results of this study indicated that statistically significance difference was observed regarding herbal medication use between public and private DOTS patients. The result shows that herbal medication use was a significant predictor for noncompliance in patients at public DOTS center. It does not have a significant association with the level of treatment compliance among patients at private DOTS clinic. This might be explained, to some extent, by low educational and economical status of patients at public DOTS center when compared to patients attending private DOTS clinic. Similar finding was registered by a study done in Nairobi(23). Similar study in South Africa describes seeing a traditional healer during TB treatment was a significant predictor of non compliance (27).

Monthly income, knowledge about TB, closure of DOTS clinic at the scheduled day and unavailability of health education were the other important determinant factors for noncompliance among patients at private DOTS clinics. The deference was significance for the variable monthly income and closure of DOTS clinic between patients served at public and private DOTS clinics.

Studies, to the contrary of our findings, have shown that monthly income and closure of DOTS clinics was a significance predictor of noncompliance among public DOTS patients (26). However a study done in Bengal shows knowledge about TB was significantly associated with noncompliance both in patients attending public and private clinics (22).

The study shows high income for patients attending private DOTS clinic have a protective effect for noncompliance. This was also reported by a study done in India (22). This may be because patients with high income status were register usually in private institutions at the start of their TB diagnosis. But a study in Arsi Zone, Ethiopia shows no difference between compliant and non compliant groups regarding monthly family income (10).

The study also found that inadequate knowledge regarding tuberculosis was significantly increase the risk of non-compliance (O.R. = 3.46, 95% C.I = 1.37, 8.75 and P = 0.008) among patients attending private health facilities. A large section of the patients (35/152) were unaware of their disease and treatment regimen. These findings indicate that patients at private DOTS do not get regular counseling and health education by the health workers regarding TB and treatment adherence. Different other studies in Ethiopia, Kenya, India, Nepal (10, 23, 26, 28) identifies adequate knowledge to TB were found to be possible protective factors for noncompliance. However a study in Malaysia shows no statistically significant differences between compliant and non compliant groups for knowledge (25).

The study also confirms that lack of counseling and health education emerged as the most important determinant of noncompliance in private DOTS. It increased chances of noncompliance 2.74 times (95% C.I = 1.14, 6.57) compared to those patients who had been counseled by health worker. This might be due to lack of independent and responsible health worker for DOTS in private health facilities. Health workers were busy by other activities to give counseling to the patient. Similar finding was registered in a study done in Nepal (26).

8. LIMITATION AND STRENGHT OF THE STUDY

The limitations to this study were, firstly the patients in the compliant group were at various stages in their treatment, and it is possible that some may have become non-compliant later. The effect of this on our results would be to reduce the differences found between the groups, even though it is compensated by patients on the last month of treatment.

Secondly, data on treatment history and possible explanatory factors in this study were based on self-report of patients. Recall bias were thus unavoidable. This may have made results more imprecise. But the study try to cross check self report data with patient registration book and pill count.

9. CONCLUSSION

The study has documented a high level of noncompliance rate among both public and private DOTS clinics. The rate of treatment noncompliance was higher in the private DOTS, as compared to public DOTS. Forgetfulness, use of addictive substance and unavailability of drug at each scheduled day were found to be significantly and independently affects the level of treatment compliance both in patients attending public and private DOTS clinics. Additionally monthly income, knowledge about TB, closure of TB clinic and health education was also the most important determinants of noncompliance in patients at private DOTS clinics. The other crucial determinant of noncompliance among patients at public DOTS was herbal medication use which does not show significant relationship with compliance among patients at private DOTS clinics.

10. RECOMMENDATION

To concerned NGO's and South Wollo Zonal Health Department

- There is a need to improve supervision to private health care facilities to ensure that all DOTS components were implemented there.
- There is need for refresher training of health care providers on the current status and challenges of tuberculosis control program, to sensitize health care workers the danger of treatment interruption and to make them accountable in their job.
- It was understood from the present study that there was some evidence regarding the negative influence of herbal medication use on treatment compliance. In this regard, there in need to work together with traditional healer, as they do not order their patients to stop medical treatment while they are on traditional treatment.

To Health Facilities or DOTS clinics

- It is mandatory to assign a responsible health worker to coordinate DOTS and balance drug stoke regularly at the clinic, who assures availability of drug always at each scheduled visit.
- Improved education for patients, their family and the general population may also improve compliance.

To Tuberculosis Patients

- Tuberculosis patients try to have a functional (active) treatment supporter who reminds them in taking their daily treatment and it is better if patients use alarming machines to click them in a schedule time. In this regard all responsible body may play a crucial role by providing alarming machines to all patients.

To Researchers

- Impact of treatment interruption on treatment outcome need to be studded

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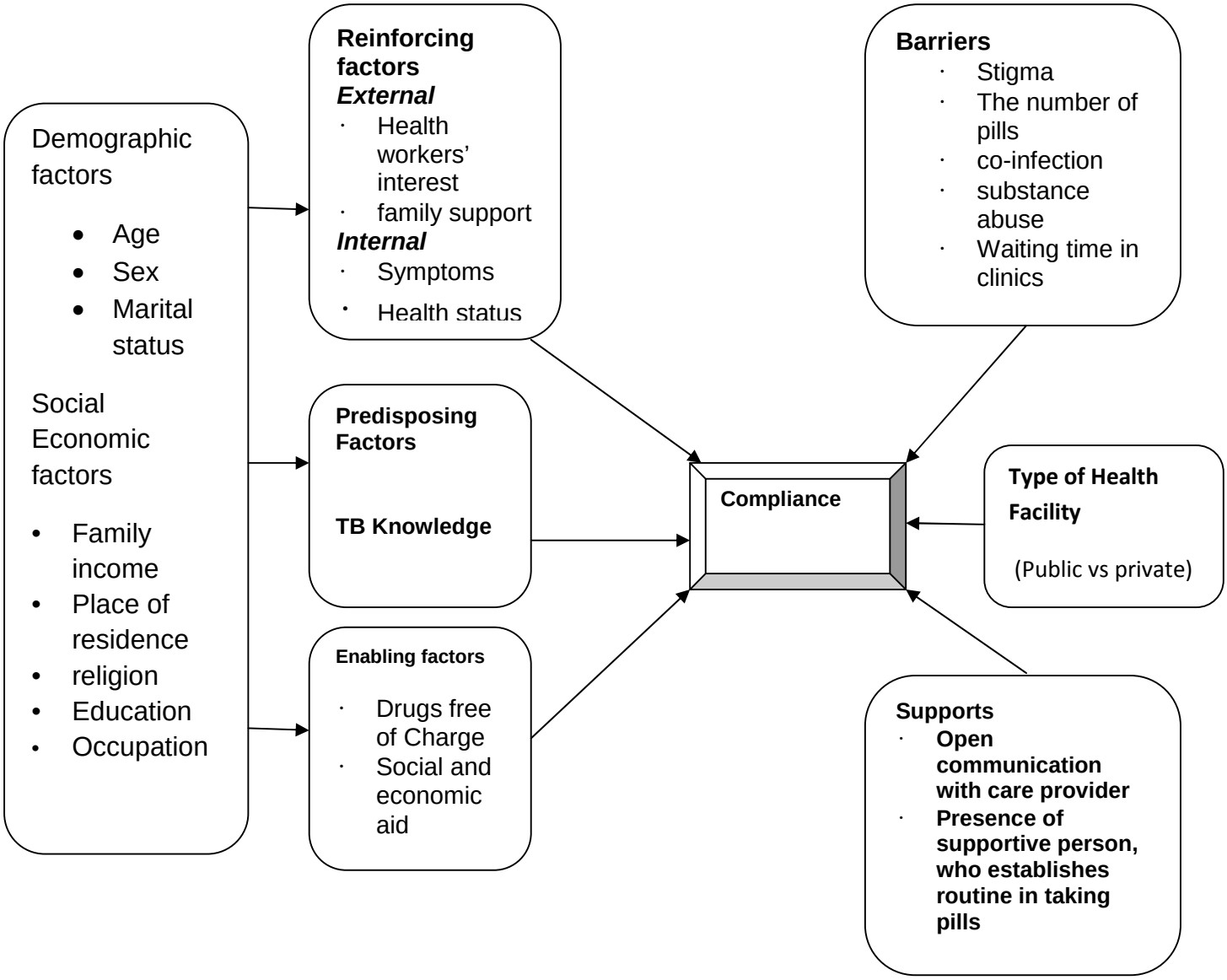
12. ANNEX

12.1. Conceptual frame work



Adopted from Barnhoorn and Adriaanse (1992)

12.2. Survey questionnaire information sheet

You are just invited to participate in a research study to be conducted by MPH student at University of Gondar. Please read the following statements and ask any thing you are unclear for it.

Name of Principal Investigator: Yimer Seid

Name of the sponsor: Amhara Regional Health Bureau

Title of the research project: Treatment compliance rate and associated factors among TB patients in public and private health institutions in Dessie and Kombolcha, North East Ethiopia.

Purpose of the research project: To assess treatment compliance rate and associated factors among registered TB patients at private and public TB treatment centers.

Procedure

Our interview will take about 15 minutes. However you can interrupt the interview at any time you want without any penalty for you.

Individuals who are below 18 year of old, and who are unable to hear and see and mentally disabled are not participated in this research.

Participation benefits: participating in this research project will not have any incentives, but you will get appropriate health service based on our recommendations for the health facility and if you adhere to the health education given during the survey you will be cured of your disease.

Participation risks: By participating in this research project, there is totally no risk that comes to one who gives information for this study. Only you may loss 15 minutes for interview.

Confidentiality Your name will not be written on the questionnaire and your answers will be kept confidential.

Person to contact: This research project will be reviewed and approved by the institutional review board of college of medicine and health science, University of Gondar. If in case you want to know more information about the research and its undertaking, you can contact the committee through the address of the advisor and/or the principal investigator below.

I. Dr. Getahun Asres(MD, MPH, DTM&H), University of Gondar, Institute of public health: Advisor
   Tel: +251911 066675_____ e-mail: Asresgetahun@yahoo.com
II. Yimer Seid , University of Gondar, Institute of public health: Principal investigator
   Tel: +251-911-730505 e-mail: yimer0505@gmail.com

Agree to participate: **Yes** ☐ **No** ☐

Signature _____ **Date**_____

12. 3. የመረጃ ቅፅ በአማርኛ ቋንቋ

የጥናቱ ርዕስ

በግልና በመንግስት የቲቢ ህክምና ተቋማት የሚገለገሉ የቲቢ ህሙማን የመድሃኒት አወሳሰድ ባህሪ እና ተያያዥ ምክንያቶች፤ ደሴ ፤ሰሜን ምስራቅ ኢትዮጲያ ::

የተመራማሪው ስም፡ ይመር ሰኢድ

የድርጅቱ ስም፡ በጎንደር ዩኒቨርሲቲ ህክምና እና ጤና ሳይንስ ኮሌጅ የህብረተሰብ ጤና አጠባበቅ ተቋም፡፡

የፕሮጀክቱ ስፖንሰር፡ የአማራ ክልላዊ መንግስት ጤና ጥበቃ ቢሮ

የጥናቱ ዓላማ ፡ የጥናቱ ዋና አላማ የቲቢ ህሙማኖች ህክምናቸውን በአግባቡ መውሰድ አለመውሰዳቸውንና ህክምናውን በአግባቡ እንዳይከታተሉ ያደረጓቸውን ምክንያቶች ለማወቅ የዳሰሳ ጥናት ለማካሄድ ነው፡፡

አተገባበር፡- እርሶ በዕጣ የተመረጡ ሲሆን ጥናቱም የሚከናወነው በእርስዎና በእኔ መካከል በሚደረግ ነጻ ቃለ ምልልስ ይሆናል፡፡ ቃለ መጠይቁ 15 ደቂቃ የሚወስድ ሲሆን ውይይቱም ሊከናወን የሚችለው የእርሶ መልካም ፈቃድ ሲገኝ ብቻ ይሆናል፡፡

እድሜአቸው ከ 18 ዓመት በታች የሆኑ ህሙማን፣ በጥና የታመሙ ህሙማን እንዲሁም አካላዊና አእምሮአዊ ችግር ያለለባቸው ህሙማኖች በጥናቱ አይሳተፉም፡፡

ጥቅም፡- በዚህ ምርምር በመሳተፍዎ በቀጥታ የሚያገኙት ጥቅም ላይኖር ይችላል ነገር ግን በጥናቱ ወቅት በሚሰጠዉ የጤና ትምህርት ተጠቃሚ ሊሆኑ ይችላሉ ይሄም መዲሃኒትዎን አስተካክለዉ እንድወስዱ በማገዝ ከህመምዎ እንድፈወሱ እገዛ ያደርጋል፡፡በተጨማሪም በጥናቱ ዉጤት መሰረት በሚሰጠዉ የመፍትሄ ሀሳብ ተጠዋሚ ሊሆኑ ይችላሉ፡፡

ሊገጥም የሚችል ችግር ወይም አለመመቸት

መጠነኛ ከሆነ የሰዓት ብክነት (15 ደቂቃ) በስተቀር በጥናቱ በመሳተፍዎ ምክንያት ምንም ዓይነት ችግር እንደማይደርስቦ ላረጋግጥሎት ዕወዳለሁ፡፡

ሚስጥራዊነት

በዚህ ምርምር ፕሮጀክት የተሰበሰበ መረጃ ሚስጥራዊ ይሆናል፡፡ በዚህ ቅፅ የእርሰዎ ስም አይፃፍበትም በተጨማሪም እርስዎ ከሚሰጡን መረጃ ጋር አይያያዝም፡፡

ያለመሳተፍ ወይም የማቋረጥ መብት

በዚህ ጥናት ያለመሳተፍ ፍፁም የሆነ መብት አለዎት ። መመለስ እማትፈልገው/እማትፈልጊው ጥያቄ ካለ አትገደድም/አትገደጅም በተጨማሪ በማንኛው ሰዓት የማቋረጥ ፍላጎትህ/ሽ የተጠበቀ ነው።

ለተጨማሪ ዝርዝር መረጃ ከዚህ በታች ባለው አድራሻ ዋና ተመራማሪውን ወይም የጥናቱን አማካሪ ማግኘት ይችላሉ።

ይመር ሰኢድ፡- ሞባይል +251911730505 - ዋና ተመራማሪ

ዶ/ር ጌታሁን አስረስ፡- ሞባይል +251911 066675 - አማካሪ

<u>ስምምነት</u>

በዚህ መሰረት በጥናቱ ለመሳተፍ ፈቃደኛ ነህ/ነሽ? ምርጫህን/ሽን ከታች በተዘጋጀው ሳጥን ውስጥ የራይት(√) ምልክት በማድርግ ግለፅ።

አዎ ፈቃደኛ ነኝ ☐

ፈቃደኛ አይደለሁም ☐

12.4. Consent Statement in English

University of Gondar

College of Medicine and Health Sciences

Institute of Public Health

How are you, my name is ----------. I am here on behalf of Yimer Seid, Master of Public Health student in Gondar University, College of Medicine and Health Sciences, Institute of Public Health.

I would like to ask you a few questions about your socio-demographic status, your treatment compliance status and some related factors as health facility, social and disease related factors for a study entitled as treatment compliance and associated factors among TB patients in public and private health institutions in Dessie, North East Ethiopia.

This will help us to improve The DOTS program both in private and public center. Your name will not be written in this form and will never be used in connection with any information you tell us.

All information given by you will be kept strictly confidential. Your participation is voluntary and you are not obligate to answer any question which you do not wish to answer. If you fill discomfort with this, please fill free to drop it any time you want. This will take about 15 minutes. Could I have your sign to continue?

Yes_____ No_____

Data collector's Name----------signature---------- date----------

THANK YOU!!

12.5. የስምምነት ማረጋገጫ ቅፅ በአማርኛ ቋንቋ

የጎንደር ዩኒቨርስቲ

የህክምና እና ጤና ሳይንስ ኮሌጅ

የህብተሰብ ጤና ተቋም

ጤና ይስጥልኝ ስሜ ..... ይባላል፡፡ የመጣሁት ከጎንደር ዩኒቨርስቲ የህብተሰብ ጤና ትምህርት ቤት ነው፡፡ በጎንደር ዩኒቨርሲቲ የህብረተሰብ ጤና ትምህርት የጥናት ቡድን አባል ነኝ፡፡

በመጀመሪያ ልገለጽሎት የምፈልገው ጥናቱን በተመለከተ ከእርስዎ ጋር አጠር ያለ ቃለ መጠይቅ ለማድረግ መፈለጌን ሲሆን ከዚህ ቀጥሎ የማቀርብሎትን መግለጫ በጥሞና እንዲያዳመጡኝ በአክብሮት እጠይቆታለሁ፡፡

የጥናቱ ዋና አላማ የሳንባ ነቀርሳና ከሳንባ ውጭ ያሉ የነቀርሳ ህሙማኖች ህክምናቸውን በአግባቡ መውሰድ አለመውሰዳቸውንና ህክምናውን በአግባቡ እንዳይከታተሉ ያደረጓቸውን ምክንያቶች ለማወቅ የዳሰሳ ጥናት ለማካሄድ ነው፡፡ ለዚህም እርሶ የተመረጡ ሲሆን ጥናቱም የሚከናወነው በእርሶና በእኔ መካከል በሚደረግ ነጻ ቃለ ምልልስ ይሆናል፡፡ ውይይቱም ሊከናወን የሚችለው የእርሶ መልካም ፈቃድ ሲገኝ ብቻ ይሆናል፡፡ በሌላ በኩል ሊመልሷቸው የማይፈልጓቸው ጥያቄዎች ካሉ ለመመለስ የማይገደዱ ሲሆን በተጨማሪም በማንኛውም ሰዓት ተሳትፎዎን ማቋረጥ ከፈለጉ ለማቋረጥ ሙሉ ዓመት ያሎት መሆኑን ላረጋግጥሎት እወዳለሁ፡፡ ይሁን እንጂ ጥናቱን በገዛ ፈቃዶ ቢቀጥሉ ከጥናቱ ውጤት እረሶ ቤተሰቦና ብሎም ሀገሮ ተጠቃሚ ሊሆኑ ይችላሉ፡፡ ከዚህ ውጭ በጥናቱ በመሳተፎ ምክኒያት ምንም ዓይነት ችግር እንደማይደርስቦ ላረጋግጥሎት ዕወዳለሁ፡፡

ይህን ካልን በጥናቱ ለመሳተፍ ፍቃደኛ ነዎት? በፊርማዎ ያረጋግጡልኝ

አዎ_____ አይደለሁም _____

አመሰግናለሁ

12.6. Interviewer administered Questionnaires in English

Part I Socio-demographic and economic characteristics of respondents

S.NO	QUESTION AND FILTERS	CODING CATEGORIES	SKIP
1	Address of the patient	Kebele_____ Registration NO _____	
2	Sex of the respondent	1. Female 2. Male	
3	Age of the respondent	_____	
4	Place of Residence	1. Urban 2. Rural	
5	Ethnicity	1. Amhara 2. Oromo 3. Tigre 4. other(specify)_____	
6	Religion	1. orthodox 2. Muslim 3. protestant 4. Other(specify)_____	
7	Marital status	1. Single 2. Married 3. Divorced/widowed	
8	Educational status	1. No formal schooling 2. Primary 3. Secondary 4. 12^{+}	
9.	Occupational status	1. Government employee 2. Self employed 3. Unemployed 4. Other (specify)_____	
10	Household monthly income in Birr	_____	

Part II Questions to assess patient related factors affecting compliance

S.NO	QUESTION AND FILTERS	CODING CATEGORIES	SKIP
11	Did you ever forget to take your TB medication	1. No 2. Yes	
12	Have you take addictive substance, like Cigarette, alcohol and khat currently?	1. No 2. Yes	
13	Knowledge about Tuberculosis(based on the sum of scores from the following six questions)	1. Adequate(if score >3) 2. Not-adequate(if score < =3)	
13.1	A person with TB can be cured	0. No 1. Yes	
13.2	Someone who has TB always has HIV/AIDS	0. Yes 1. No	
13.3	You can die from TB if you do not take your drugs regularly	0. No 1. Yes	
13.4	TB treatment usually takes at least 6 month.	0. No 1. Yes	
13.5	TB medicine is taken daily	0. No 1. Yes	
13.6	You should stop taking TB drugs as soon as you feel better	0. Yes 1. No	

Part III Questions to assess health-care and system related factors affecting compliance

S.NO	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
14	Does TB clinic opening time convenient for you?	1.Yes 2. No	
15	What would be the most convenient TB clinic opening time for you?	_____	
16	How far is your home to your treatment center(in KM)	_____Km	
17	How much time do you usually wait at the TB clinic before being attended?	1. Less than 1 hour 2. 0ne to two hour 3. Greater than 2 hour	
18	What is your means of transportation to your treatment center?	1. On foot 2. Public transport 3. Others(specify)_____	
19	When you come to pick your drugs at the TB clinic, what would you say about the availability of drugs here?	1. Always available 2. Not always available	
20	Did you ever face a problem of closing of DOTS center or Absence of health workers in this unit?	1. No 2. Yes	
21	Have you ever get health education about your treatment, side effect of drugs, danger of non compliance etc. by HCWs?	1. No 2. Yes	
22	How would you rate the attitude of HWs who attends you at the health facility?	1. Very friendly 2. Friendly 3. Unfriendly	

Part IV Questions to assess social related factors.

S.NO	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
23	Did you inform your friends/relatives that you are on TB treatment?	1. No 2. Yes	
24	If NO fro Q-22, Is that due to fear of being Isolated (stigma)?	1. No 2. Yes	
25	Who provide you support and encouragement to continue and complete your anti-TB treatment?	1. health facility worker 2. Health extension worker 3. A family member 4. Community leader 5. Religious leader 6. Has no treatment supporter	
26	Have you ever tried traditional medicine for your TB illness?	1. No 2. Yes	
	Part V treatment and disease related factors		
27	Did you experience any side effect when you were taking TB treatment?	1. No 2. Yes	
28	If yes to Q-26, which side effect did you experience?	1. Skin rash 2. Headache and dizziness 3. Yellow eyes 4. Vomiting and confusion 5. Orange/red urine 6. Other(specify)_____	
29	From the day you started taking your TB medicines how long did it take you before you fell well?	_____week	

Part V cont….

S.NO	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
30	Disease category? (circle appropriately according to treatment card or TB register)	1. New 2. Re-treatment	
31	Disease classification?(circle appropriately according to treatment card or TB register)	1. PTB-SM+ 2. PTB-SM- 3. EPT	
32	HIV/AIDS status(as indicated on treatment card or TB register)	1. Positive 2. Negative 3. Not Indicated/known	
33	Was the patient taking other medicines Besides TB treatment?	1. No 2. Yes	
34	If Yes for Q-32, which medicine was the patient taking?	1. HAART 2. Anti-Hypertensive 3. Psychiatric Drugs 4. Others(specify)	

Part VI. Compliance status of the respondents, to be filled by cross-checking with patient's registration Book and Pill counting.

S.NO	QUESTION AND FILTERS	CODING CATEGORIES	SKIP
35	When did you start taking Anti-TB drug	Date/month/year E.C ____/_____/_____	
36	For how long did you take TB drug	_____day	
37	Did you miss any of your daily TB medication	1. No 2. Yes	
38	If yes for Q-32 and Q-36, Is those missed doses are really TB drugs?	1. Yes 2. No	
39	If yes for Q-36, how many days did you miss to take your medication?	----------day	
40	Why did you miss taking your medications?	1._____ 2. _____ 3._____ 4_____ 5._____ 6.	

Thank you

(Name Of data Collector _____Date _____Sign___

12.7. የአማርኛ ቋንቋ መጠይቅ

ክፍል አንድ፡- የህሙማኑን የግልና የማህበራዊ ሁኔታ በተመለከተ የቀረበ መጠይቅ

ተ.ቁ	የጥያቄዎች ዝርዝር	የመልስ ኮድ ቁጥር	ወደ እለፍ
1	የህሙማኑ አድራሻ	ቀበሌ_____ የሰፈር ስም_____ የህክምና መዝገብ ቁጥር_____	
2	የህሙማኑ ፆታ	1. ሴት 2. ወንድ	
3	የህሙማኑ ዕድሜ	_____ዓመት	
4	የመኖሪያ ቦታ	1. ከተማ 2. ገጠር	
5	ብሄር	1. አማራ 3. ኦሮሞ 2- ትግሬ 4. ሌላ(ይገለፅ)_____	
6	ሐይማኖትዎ	1. ኦርቶዶክስ 2. እስልምና 3-ፕሮቴስታንት 4. ሌላ(ይገለፅ) _____	
7	የህሙማኑ የጋብቻ ሁኔታ	1. ያላገባ/ች 2. ያገባ/ች 3- የተፋታ/በሞት የተለየ/ች	
8	የህሙማኑ የትምህርት ደረጃ	1. መደበኛ ትምህርት ያልተማረ/ች 2. አንደኛ ደረጃ 3. ሁለተኛ ደረጃ 4. ከ 12ኛ ክፍል በላይ	
9.	የህሙማኑ የስራ ሁኔታ	ነ- የመንግስት ሰራ 2. የግል ተቀጣሪ 3- ስራ አጥ 4. ሌላ(ይገለፅ) _____	
10	የቤተሰቡ የወር ገቢ በ ብር/በአይነት	_____	

ክፍል ሁለት፡- ከህሙማኑ የግል ችግሮች ጋር የተያያዙ የበሽተኛዉን የመድሃኒት አወሳሰድ ባህሪ የሚወስኑ ሁኔታዎችን በተመለከተ የቀረበ መጠይቅ

ተ.ቁ	የጥያቄዎች ዝርዝር	የመልስ ኮድ ቁጥር	ወደ እለፍ
11	መድሃኒትዎን መዉሰድ ረስተዉ ያዉቃሉ?	1- የለም 2. አዎ	
12	ሱስ የሚያሲዙ ነገሮችን እንደ ጫት፣ ሲጋራ እና የአልኮል መጠጥ አሁን ይጠቀማሉ?	1. የለም 2. አዎ	

13	ህሙማኑ ለቲቢ ያለዉ እዉቀት ምን ያክል ነዉ(ከታች በተዘረዘሩት ስድስት ነጥቦች ዉጤት መሰረት የሚሞላ)	1. በቂ ነዉ(ስኮር >3) 2. በቂ አይደለም (ስኮር < =3)	
13.1	ቲቢ ሙሉ በሙሉ የሚድን በሽታ ነዉ?	0. አይደለም 1. ነው	
13.2	ቲቢ ያለበት ህሙማን ኤድስ አለበት ብሎ መደምደም ይቻላል?	0. ይቻላል 1. አይቻልም	
13.3	መድሃኒቱን በትክክል የማይወስድ የቲቢ በሽተኛ ሊሞት ይችላል?	0. የለም 1. አዎ	
13.4	የቲቢ ህክምና በትንሹ 8 ወር ይፈጃል?	0. አይደለም 1. አዎ	
13.5	የቲቢ ህክምና ቀን በቀን የሚወሰድ ነዉ ?	0. አይደለም 1. ነው	
13.6	ህመሙ ቀድሞ ከተሸለህ/ሽ የቲቢን መድሃኒት መዉሰድ ማቆም ትችላለህ/ሽ?	0. አዎ 1. አይደለም	

ክፍል ሶስት፡- የህሙማኑን የመድሃኒት አወሳሰድ ባህሪ የሚወስኑ ከጤና ተቋሙ ጋር ተያያዥነት ያላቸዉ ሁኔታዎችን በተመለከተ የቀረበ መጠይቅ

ተ.ቁ	የጥያቄዎች ዝርዝር	የመልስ ኮድ ቁጥር	ወደ እለፍ
14	የቲቢ ክሊኒኩ የሚከፈትበት ሰዓት ላንተ አመች ነዉ?	1. አዎ 2. አይደለም	
15	የቲቢ መድሃኒትህን ለመዉሰድ አመች የሚሆንልህ ጊዜ ስንት ሰዓት ላይ ነዉ?	በኢትዮጲያ ሰዓት ----------	
16	መኖሪያ ቤትህ የቲቢ መድሃኒት ከምትከታተልበት የጤና ተቋም ምን ያክል ይርቃል(በኪሎ ሜትር)?	_____ኪ.ሜ	
17	መድሃኒትህን ለመዉሰድ/ለመቀበል ባማካኝ ምን ያክል ጊዜ በጤና ተቋሙ ትጠብቃለህ/ሽ?	1. ከአንድ ሰዓት በታች 2. ከአንድ እስከ ሁለት ሰዓት 3. ከሁለት ሰዓት በላይ	
18	መድሃኒትህን ለመዉሰድ ስትመጣ ባብዛህኛዉ የምትጠቀምበት መጓጓዣ ምንድን ነዉ?	1. በእግር 2. በህዝብ ትራንስፖርት 3. ሌላ(ይገለፅ)----------	

19	መድሃኒትህን ለመዉሰድ ስትመጣ በዚህ ተቋም ስላለዉ የመድሃኒት አቅርቦት ምን ትላለህ?	1. ሁልጊዜ አለ 2. አልፎ አልፎ የለም እባላለሁ	
20	መድሃኒት የምትወስድበት ክፍል መዘጋት ወይም የጤና ባለሙያዉ አለመኖር ችግር አጋጥሞህ ያዉቃል?	1. የለም 2. አዎ	
21	መድሃኒቱን በትክክል አለመዉሰድ ስለሚያስከትለዉ ችግር የጤና ትምህርት በጤና ባለሙያዉ አግኝተዉ ያዉቃሉ?	1. አዎ 2. የለም	
22	የጤና ባለሙያዎች ለቲቢ ህሙማን ያላቸዉን አመለካከት እንደት ትመዝነዋለህ?	1. ጥሩ ነዉ 2. መጥፎ ነዉ	

ክፍል አራት፡- የህሙማኑን የመድሃኒት አወሳሰድ ባህሪ የሚወስኑ ከማህበራዊ ጉዳዮች ጋር ተያያዥነት ያላቸዉ ሁኔታዎችን በተመለከተ የቀረበ መጠይቅ

ተ.ቁ	የጥያቄዎች ዝርዝር	የመልስ ኮድ ቁጥር	ወደ እለፍ
23	የቲቢ መድሃኒት እየወሰድክ/ሽ መሆኑን ለቤተሰብህ/ሽ ወይም ለጓደኞችህ ነግረሀቸዋል?	1. የለም 2. አዎ	መልስዎ አዎ ከሆነ ወደ 25
24	ለጥያቄ ቁጥር 22 የለም ከሆነ መልስዎ፣ ምክንያቱ መገለልና መድሎ ይሆን)?	1. የለም 2. አዎ	
25	መድሃኒትህን በትክክል እንድትወስድ የሚያግዝህ የህክምና ረዳትህ/ሽ ማን ነዉ	1. የጤና ባለሙያ 2. የጤና ኤክስቴንሽን ሰራተኛ 3. የቤተሰብ አባል 4. የማህበረሰቡ ተወካይ 5. የሀይማኖት መሪ 6. የለኝም	
26	ለቲቢ ህመመዎ የባህላዊ ህክምና ተጠቅመዉ ያዉቃሉ	1. የለም 2. አዎ	

ክፍል አምስት፡- የበሽተኛዉን የመድሃኒት አወሳሰድ ባህሪ የሚወስኑ ከበሽታዉ ባህሪ እና ከ ህክምናዉ ጋር ተያያዥነት ያላቸዉ ሁኔታዎችን በተመለከተ የቀረበ መጠይቅ			
27	የቲቢ መድሃኒት ስትወስድ ከ መድሃኒቱ ጋር ተያያዥነት ያለዉ የጎንዮሽ ችግር አጋጥሞህ/ሽ ያዉቃል?	1. የለም 2. አዎ	መልስዎ የለም ከሆነ ወደ 29
28	ለጥያቄ ቁጥር 26 አዎ ከሆነ መልስዎ፤ የትኛዉ የጎንዮሽ ችግር ነዉ ያጋጠመዎት?	1. የቆዳ ሽፍታ 2. እራስ ምታትና ማዞር 3. የአይን ቢጫ መሆን 4. ማስታዎክና ብዥታ 5. የሽንት መቅላት 6. ሌላ(ይገለፅ)_____	
29	የቲቢ መድሃኒት መዉሰድ ከጀመሩ በኋላ ከህመሙ ለማገገም ምን ያክል ጊዜ ፈጅቶበዎታል?	_____ሳምንት	
30	ህመሙኑ ከ የትኛዉ የቲቢ ታካሚዎች ምድብ ይመደባል? (የህመሙኑን የህክምና ካርድ ወይም መዝገብ በማየት ይመለስ)	1. ከአዲስ የቲቢ ህመማን 2. የድጋሚ የቲቢ ህመማን	
31	ህመሙኑ የትኛዉ የቲቢ አይነት ነዉ ያለበት? (የህመሙኑን የህክምና ካርድ ወይም መዝገብ በማየት ይመለስ)	1. በአክታ የተረጋገጠ የሳንባ ቲቢ 2. በአክታ ያልተረጋገጠ የሳንባ ቲቢ 3. ከሳንባ ዉጭ የሆኑ ቲቢ	
32	የቲቢ ህመሙኑ የ ኤችአቪ ኤድስ ሁኔታ ይታወቃል? (የህመሙኑን የህክምና ካርድ ወይም መዝገብ በማየት ይመለስ)	1. ፖዝቲቭ 2. ነጋቲቭ 3. አይታወቅም/አልተገለፀም	
33	ከቲቢ መድሃኒት ዉጭ ሌላ መድሃኒት ይወስዳሉ?	1. የለም 2. አዎ	
34	ለጥያቄ ቁጥር 32 አዎ ከሆነ መልስዎ የትኛዉን መድሃኒት ነዉ የሚወስዱት (የህመሙኑን የህክምና ካርድ ወይም መዝገብ በማየት ይረጋገጥ)	1. የኤችአቪ መድሃኒት 2. የደም ግፊት መድሃኒት 3. የአእምሮ በሽታ መድሃኒት 4. ሌላ(ይገለፅ)----------	

ክፍል ስድስት፡ የቲቢ ህሙማኑ ከሚሰጠዉ መድሃኒት ጋር ያለዉ የመተማመን ሁኔታ በተመለከተ የቀረበ መጠይቅ

ተ.ቁ	የጥያቄዎች ዝርዝር	የመልስ ኮድ ቁጥር	ወደ እለፍ
35	የቲቢ በመድሃኒት መዉሰድ የጀመርከው/ሽዉ መቼ ነዉ (የህሙማኑን የህክምና ካርድ ወይም መዝገብ በማየት ይረጋገጥ)	ቀን/ ወር/ ዓመት በኢትዮጲያ የቀን አቆጣጠር _____/_____/_____/	
36	የቲቢ መድሃኒት መዉሰድ ከጀመሩ ምን ያክል ጊዜ ሆነዎት(ከጀመሩበት እስከ ዛሬ ቀን ድረስ ያለዉ ጊዜ)	_____ቀን	
37	መድሃኒትዎን መዉሰድ/መዋጥ ያቋረጡበት ጊዜ ይኖር ይሆን	1. አዎ 2. የለም	
38	ያቋረጡት መድሃኒት የቲቢ ስለመሆኑ እርግጠኛ ነዎት	1. አዎ 2. የለም	
39	ለጥያቄ ቁጥር 36 አዎ ከሆነ መልስዎ ምን ያክል ጊዜ አቋርጠዋል/ረስተዋል((የህሙማኑን የክትትል መዝገብ በማየት ወይም ትርፍ መድሃኒት በመቁጠር ይረጋገጥ)	----------ቀን	
40	መድሃኒትዎን ለማቋረጥ ምክንያት የሆነዎት ነገር ምንድን ነበር?		

ፈቃደኛናል፡ በጣም አመሰግናለሁ፡፡

የጤና ተቋሙ አይነት፡ የግል ☐ የመንግስት ☐

የመረጃ ሰብሳቢዉ ስም---------- ቀን ----------

ፊርማ----------

13. DECLARATION

I, the undersigned, senior MPH student declare that this thesis report is my original work in partial fulfillment of the requirement for the degree of Master of Public Health.

Name: Yimer Seid

Signature: _____

Place of submission: Institute of public Health, College of Medicine and Health Sciences, University of Gondar.

Date of Submission: _____

This thesis has been submitted for examination with my approval as university advisor.

Advisors

Name	Signature
Dr. Getahun A. (MD, MPH, DTM&H)	_____